REGISTRATION REPORT

Part B

Section 1: Identity
Section 2: Physical and chemical properties
Section 4: Further information

Detailed summary of the risk assessment

Product code: GLOB1310aH

Product name(s): Glosset Ace

Chemical active substance:

Aclonifen, 540 g/L

Flufenacet, 60g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: Globachem NV

Submission date: December 2021

MS Finalisation date: 25/08/2022

After commenting: 14/12/2022

Version history

When	What
December 2021	Initial submission by the applicant for approval of new product.
August 2022	First zRMS PL evaluation
December 2022	Corrections made by zRMS PL after commenting round

Table of Contents

State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- data gap 1
- data gap 2
- data gap 3

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Globachem NV
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium
Contact:

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Aclonifen

Aclonifen min. 980 g/kg

The source of the active ingredient has been confirmed to be equivalent to the annex I source by the RMS Germany.

Further information relating to the impurities is confidential information – data is provided separately (Part C).

1.2.3.2 Flufenacet

Flufenacet min. 950 g/kg

Further information relating to the impurities is confidential information – data is provided separately (Part C).

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Glosset Ace

Company code number: GLOB1310aH

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 0-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Aclonifen	540	515-565	551	43.97
Flufenacet	60	54-66	63.2	5.15

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (98% for aclonien, 95% for flufenacet)

** Based on the density of the formulation = 1.2282

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 0-2: Information on Aclonifen

Type	Name/Code Number
ISO common name	Aclonifen
CAS No.	74070-46-5
EC No.	277-704-1
CIPAC No.	498

Table 0-3: Information on Flufenacet

Type	Name/Code Number
ISO common name	Flufenacet
CAS No.	142459-58-3

Type	Name/Code Number
EC No.	-
CIPAC No.	588

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

There are no safeners or synergists in the formulation. Information regarding the co-formulants is confidential.

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension concentrate [Code: SC]

1.6 Function (KCP 1.6)

Herbicide

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a yellow opaque, with a faint sweet odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature higher than 400°C. It has a pH value around 6.48 at 20 °C; in aqueous solution (1%) it has a pH value around 6.64 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. ~~The 2-weeks accelerated temperature test showed the formulation does not change its characteristics.~~ A 2 years shelf life at ambient temperature is currently ongoing at DNAL (study plan number DNA5851, expected finalized report in October 2022). Its technical characteristics are acceptable for a *SC* formulation.

The intended concentration of use is 0.67% to 2.% for the high rate (2L formulation in 300 and 100L water/ha, respectively) and 0.5% to 1.5% for the low rate (1.5L formulation in 300 and 100L water/ha, respectively)

No tank mixes are required for GLOB1310aH.

Phenol had been identified as a relevant impurity of the active ingredient Aclonifen in the EFSA Scientific report (2008 149, 1-80 conclusion on the peer review of aclonifen). However, as this impurity is not present in the source of Globachem (please refer to part C and technical equivalence report), its content is not reported in the below physico-chemical results.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Implications for labelling: None.
Accepted
Not classified, according to CLP Regulation, for physical-chemical hazard.

Compliance with FAO specifications:

The product GLOB1310aH complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C. It contains 540 g/L Aclonifen, 60 g/L Flufenacet and all other co-formulants were the same and had the same concentration.
Evaluator's comments
The phys.-chem. properties of GLOB1310aH (Product name: Glosset Ace) have been determined under GLP and according to test methods internationally recognized such as CIPAC methods, the 'EC methods' (Regulation (EC) No. 440/2008) and OECD methods.
There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient content (Aclonifen and Flufenacet) nor the technical properties were changed.
~~The 2-weeks accelerated temperature test showed the formulation does not change its characteristics.~~
The sample appearance and packaging remained unchanged post accelerated storage for eight weeks at 40°C±2°C.
The user properties of the formulation are acceptable for a suspension concentrate (SC) both initially and after storage for 8 weeks at 40°C.
A 2 years shelf life study at ambient temperature is currently ongoing.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	The samples arrived in good condition with no signs of any leaks, visual seepage or panelling. Sample DNA5850/1 was a uniform yellow liquid. The sample was opaque, coating the walls of the beaker and free flowing. There were no signs of separation into oil, cream, sediment, claying or suspended solids. The sample had a faint sweet odour.	Y	Pomeroy, D. 2020	**Accepted** Visual inspection of colour, physical state and odour were performed.
Active Ingredient Determination Aclonifen	David Norris In House Methodology Validated in Study DNA5853	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	543.7g/L (Equating to 100.7% of the Declared Content)	Y	Pomeroy, D. 2020	**Accepted** The analytical method which was used to determined active ingredient content – Aclonifen - was validated in GLP laboratory (in house analytical method DNA5853). The content of active ingredient was determined by HPLC -PDA. The initial concentration of Aclonifen (pre storage sample DNA 5850/1) was 543.7 g/L equivalent to 100.7% of the declared amount.
Active Ingredient Determination Flufenacet	David Norris In House Methodology Validated in Study DNA5853	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	61.55g/L (Equating to 102.6% of the Declared Content)	Y	Pomeroy, D. 2020	**Accepted** The analytical method which was used to determined active ingredient content – Flufenacet - was validated in GLP laboratory (in house analytical method DNA5853). The content of

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						active ingredient was determined by HPLC -PDA. The initial concentration of Flufenacet (pre storage sample DNA 5850/1) was 61.55 g/L equivalent to 102.6% of the declared amount.
Impurity Determination Phenol	David Norris In House Methodology Validated in Study DNA5853	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Not Detected (<0.5g/Kg equivalent to <0.93g/Kg in Active Ingredient (Aclonif-en) as Manufactured)	Y	Pomeroy, D. 2020	**Accepted** The analytical method which was used to determined impurity content – phenol - was validated in GLP laboratory (in house analytical method DNA5853). The content of impurity was determined by HPLC -DAD instrument. The initial concentration of test item (pre storage sample DNA 5850/1) did not contain phenol above LOQ level of 0.5 g/Kg equivalent to 0.93 g/Kg in the active ingredient (Aclonifen) as manufactured.
Explosive properties (KCP 2.2.1)	Theoretical certificate	/	No explosive properties	N	Pomeroy, D. 2021	**Accepted** The test was not performed. Theoretical evaluation based on the available information for example Safety Data Sheets, scientific

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						information. According to CLP Regulation: "Mixture shall not be classified as explosive if: - there are no chemical groups associated with explosive properties present in the molecule". The substances/mixtures which are part of the test item are not classified as explosives. There are also no chemical groups associated with the explosives properties in test item.
Oxidizing properties (KCP 2.2.2)	Theoretical certificate	/	No oxidising properties	N	Pomeroy, D. 2021	**Accepted** The test was not performed. Theoretical evaluation based on the available information for example Safety Data Sheets, scientific information. The substances/mixtures which are part of the test item are not classified as oxidising.
Flash point (KCP 2.3.1)	EEC A9	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Not highly flammable	Y	Pomeroy, D. 2020	**Accepted** The A9 test was performed "Flammability for liquids". A closed cup Flash Point apparatus was used. Test item did not flash below

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						100°C and therefore is considered not higly flammable.
Flammability (KCP 2.3.2)	-	-	Not applicable for an SC formulation.			**Accepted** Not applicable for an SC formulation.
Self-heating (KCP 2.3.3)	EEC A15	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Not highly flammable The formulation did not auto-ignite below 400°C	Y	Pomeroy, D. 2020	**Accepted** Tets item (pre storage sample DNA5850/1) did not auto-ignite below 400°C and is therefore considered not highly flammable.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Neat: pH 6.48 at 20°C Acidity or alkalinity not required as the pH value of the 1 % diluted solution is between pH6 and pH8.	Y	Pomeroy, D. 2020	**Accepted** The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for either 1 % dilution or neat formulation). The pH value of the 1% diluted solution and neat formulation is about 6.5 at 20°C and therefore acidity/alkalinity test was not required.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	1% Dilution: pH 6.64 at 20°C	Y	Pomeroy, D. 2020	**Accepted**

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>Viscosity
(KCP 2.5.1)</td><td>OECD 114</td><td>Aclonifen 540 g/L, Flufenacet 60 g/L, SC

(Batch GLO-20F-2306A)</td><td>Non-Newtonian Liquid</td><td>Y</td><td>Pomeroy, D. 2020</td><td>Accepted
The viscosity was determined at various speed shear rates. Test was conducted at 20°C and 40°C. The rotational viscometer was used for determination of the dynamic viscosity of test sample before storage.

Corrected viscosity at 20°C±0.1°C
<table>
<tr><th>Speed R.P.M.</th><th>Shear Rate/s</th><th>Corrected viscosity mPa*s</th></tr>
<tr><td>0.3</td><td>0.1</td><td>22384</td></tr>
<tr><td>0.5</td><td>0.17</td><td>15423</td></tr>
<tr><td>0.6</td><td>0.2</td><td>14465</td></tr>
<tr><td>1.0</td><td>0.34</td><td>10162</td></tr>
<tr><td>1.5</td><td>0.51</td><td>7707</td></tr>
<tr><td>2.0</td><td>0.68</td><td>6314</td></tr>
<tr><td>2.5</td><td>0.85</td><td>5398</td></tr>
<tr><td>3.0</td><td>1.02</td><td>4809</td></tr>
<tr><td>4.0</td><td>1.36</td><td>3933</td></tr>
<tr><td>5.0</td><td>1.7</td><td>3405</td></tr>
<tr><td>6.0</td><td>2.04</td><td>3009</td></tr>
<tr><td>10.0</td><td>3.40</td><td>2188</td></tr>
<tr><td>12.0</td><td>4.08</td><td>1949</td></tr>
</table>
Corrected viscosity at 40°C±0.1°C
<table>
<tr><th>Speed R.P.M.</th><th>Shear Rate/s</th><th>Corrected viscosity mPa*s</th></tr>
<tr><td>0.3</td><td>0.1</td><td>14525</td></tr>
<tr><td>0.5</td><td>0.17</td><td>9890</td></tr>
<tr><td>0.6</td><td>0.2</td><td>9376</td></tr>
<tr><td>1.0</td><td>0.34</td><td>6708</td></tr>
</table></td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						1.5 | 0.51 | 5084 2.0 | 0.68 | 4375 2.5 | 0.85 | 3773 3.0 | 1.02 | 3215 4.0 | 1.36 | 2833 5.0 | 1.7 | 2499 6.0 | 2.04 | 2062 10.0 | 3.40 | 1646 12.0 | 4.08 | 1355 20.0 | 6.80 | 1132 30.0 | 10.20 | 806
Surface tension (KCP 2.5.2)	EEC A5	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	At 20 ± 0.1°C: 38.00 ± 0.109mN/m At 25 ± 0.1°C: 38.58 ± 0.156mN/m	Y	Pomeroy, D. 2020	**Accepted** The surface tension shall be determined at the highest in use concentration. The surface tension of test item was determined at the highest in use concentration (2.0 L of formulation in 100 L of water). The surface tension determined at temperature 20°C and 25°C was below 60 mN/m, the product is ~~not~~ surface active.
Relative density (KCP 2.6.1)	EEC A3	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	At 20.0°C: 1.2282g/mL At 40.0°C: 1.2192g/mL	Y	Pomeroy, D. 2020	**Accepted**
Bulk density (KCP 2.6.2)	-	-	Not applicable for an SC formulation.	-		**Accepted** Not applicable for an SC

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							formulation.
Storage Stability after 14 days at 54º C (KCP 2.7.1)	-	-	**See below after 8 weeks at 40°C.**		-		
Stability after storage for other periods and/or temperatures (KCP 2.7.2) **8 weeks at 40°C**	-	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Appearance & Stability of Packaging	The sample appearance and packaging remained unchanged post accelerated storage for eight weeks at 40ºC±2ºC, from the Pre Storage sample, DNA5850/1 after inversion.	-	Pomeroy, D. 2020	**Accepted** There were no signs of separation into oil, cream, sediment, claying or suspended solids. The appearance of the sample remained unchanged post accelerate storage at 40°C±2°C for eight weeks after inversion. The sample was stored in a white HDPE/C 1L tall form bottle. The bottle showed no signs of leaks or visual seepage and no signs of panelling. The sample packaging remained unchanged post accelerated storage at 40°C÷2°C for eight weeks. The analytical method which was used to determined active ingredient (Aclonifen) content was validated in GLP laboratory (analytical method DNA5853). The content of
			Active Ingredient Determination Aclonifen	548.0g/L (Equating to 101.5% of the Declared Content)			
			Active Ingredient Determination Flufenacet	61.20g/L (Equating to 102.0% of the Declared Content)			
			Impurity Determination Phenol	Not Detected (<0.5g/Kg equivalent to <0.93g/Kg in Active Ingredient (Aclonifen) as Manufactured)			
			pH Determination	1% Dilution: pH 6.49 at 20°C Neat: pH 6.26 at 20°C			
			Spontaneity of Dispersion For Aclonifen	In CIPAC Water A: 95.85% In CIPAC Water D: 96.44%			
			Spontaneity of Dispersion For Flufenacet	In CIPAC Water A: 95.72% In CIPAC Water D: 96.20%			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			Suspensibility For Aclonifen	At the high application in CIPAC Water D: 99.42% At the low application in CIPAC Water D: 102.9%			active ingredient was determined by HPLC-PDA. The initial concentration of Aclonifen was 543.7 g/L, the concentration of Aclonifen after 8 weeks of storage at temperature 40±2°C was 548.0 g/L. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. No significant change in content of the active substance -Aclonifen was observed following 8 weeks storage at 40±2°C. The analytical method which was used to determined active ingredient (Flufenacet) content was validated in GLP laboratory (analytical method DNA5853). The content of active ingredient was determined by HPLC-PDA. The initial concentration of Flufenacet was 61.55 g/L, the concentration of Flufenacet after 8 weeks of storage at temperature 40±2°C was 548.0 g/L.
			Suspensibility For Flufenacet	At the high application in CIPAC Water D: 99.39% At the low application in CIPAC Water D: 102.8%			
			Pourability	Poured Residue: 3.6442% Primary Water Rinsed Residue: 0.4274% Secondary Water Rinsed Residue: 0.0573% Acetone Rinsed Residue: 0.0036%			
			Wet Sieve Test	Mean of two results: 0.1286%			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. No significant change in content of the active substance -Flufenacet was observed following 8 weeks storage at 40±2°C. The analytical method which was used to determined impurity content – phenol - was validated in GLP laboratory (in house analytical method DNA5853). The content of impurity was determined by HPLC -DAD instrument. The concentration of test item after storage at 40±2°C did not contain phenol above LOQ level of 0.5 g/Kg equivalent to 0.93 g/Kg in the active ingredient (Aclonifen) as manufactured. No significant change in the pH 1% w/w solution and neat formulation was observed after 8 weeks of storage at 40±2°C.

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the Aclonifen using both CIPAC Water A nad CIPAC Water D post accelerated storage. The above mentioned criteria were also met for the Flufenacet using both CIPAC Water A nad CIPAC Water D post accelerated storage. Suspensibility/ dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							active substance still in suspension the validated analytical method (study code DNA5853) was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for Aclonifen – post storage – 8 weeks at 40°C (the analysis were performed for active substance Aclonifen at high concentration in CIPAC Water D and low concentration in CIPAC Water D). The above mentioned criteria for suspensibility were alos met for Flufenacet – post storage – 8 weeks at 40°C (the analysis were performed for active substance Flufenacet at high concentration in CIPAC Water D and low concentration in CIPAC Water D). Pourability - the data are required to demonstrate that

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							the user can make use of the maximum amount of the preparation and that an excessive amount of the material does not remain in the container. Acceptable limits: Maximum 5 % residue was met. The residue remaining in the commercial pack following recommended rinsing procedures is acceptable. A wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The above mentioned criteria was met (mean wet sieve residue was 0.1286%) for the test item after storage at 8 weeks at 40°C.
Minimum content after heat stability testing	-		**See above after 8 weeks at 40°C**		-		

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.3)							
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	The sample appearance remained unchanged post low temperature storage. The test was repeated with the addition of a crystal of Aclonifen after 24 hours. The crystal dissolved, the sample appearance remained unchanged post low temperature storage with Aclonifen crystal addition.		Y	Pomeroy, D. 2020	**Accepted** Suspensibility and wet sieve test should be determined after storage. The test item appeared unchanged post low temperature storage for 7 days at 0°C and 3 hours at room temperature. The sample remained an opaque uniform yellow liquid with no signs of separation into oil, cream, sediment, claying, suspended solids or crystals. The test item with the addition of a crystal of Aclonifen after 24 hours appeared unchanged post Low Temperature storage for 7 days at 0°C and 3 hours at room temperature. The crystal dissolved and the sample remained an opaque uniform yellow liquid with no signs of separation into oil, cream sediment, claying, suspended solids or crystals. Suspensibility/ dispersion stability is determined to demonstrate
			Suspensibility For Aclonifen	At the high application in CIPAC Water D: 103.3% At the low application in CIPAC Water D: 102.5%			
			Suspensibility For Flufenacet	At the high application in CIPAC Water D: 103.1% At the low application in CIPAC Water D: 102.1%			
			Wet Sieve Test	Mean of two results: 0.1286% Editorial error should 0.190%			

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
							that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substance still in suspension the validated analytical method (study code DNA5853) was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for Aclonifen – post low temperature storage (the analysis were performed for active substance Aclonifen at high concentration in CIPAC Water D and low concentration in CIPAC Water D). The above mentioned criteria for suspensibility were alos met for Flufenacet – post low temperature storage (the analysis were performed for active substance Flufenacet at high

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						concentration in CIPAC Water D and low concentration in CIPAC Water D). A wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The above mentioned criteria was met (mean wet sieve residue was 0.190%) for the low temperature storage sample.
Ambient temperature shelf life (KCP 2.7.5)			A 2 years shelf life study at ambient temperature is currently ongoing at DNAL (DNA5851); the results will be provided when available (October 2022)			A years shelf life study at ambient temperature is currently ongoing. The resilts of 2 years shelf life study at ambient temperature will be evaluated when the results will be provided by the sponsor.
Shelf life in months (if less than 2 years)	-		-	-		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.6)						
Wettability (KCP 2.8.1)	-	-	Not required as GLOB1310aH is not a solid formulation.	-		**Accepted** Not required (Wettability is determined to ensure the preparation is readily wetted in use. The data are required for solid preparations which are to be dispersed in water.)
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	At the Low Application Rate After 1 minute: 5.0mL After 12 minutes: 5.0mL At the High Application Rate After 1 minute: 10.0mL After 12 minutes: 10.0mL	Y	Pomeroy, D. 2020	**Accepted** Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable limits: max 60 mL foam after 1 minute. The criteria were met for thr minimum application rate and for the maximum application rate.
Suspensibility Aclonifen (KCP 2.8.3.1)	CIPAC MT 184	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	At the high application in CIPAC Water D: 101.8% At the low application in CIPAC Water D: 101.7%	Y	Pomeroy, D. 2020	**Accepted** Suspensibility/ dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						determination of mass of active substance still in suspension the validated analytical method (study code DNA5853) was used (HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for Aclonifen – pre storage (the analysis were performed for active substance Aclonifen at high concentration in CIPAC Water D and low concentration in CIPAC Water D).
Suspensibility Flufenacet (KCP 2.8.3.1)	CIPAC MT 184	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	At the high application in CIPAC Water D: 101.4% At the low application in CIPAC Water D: 101.4%	Y	Pomeroy, D. 2020	**Accepted** Suspensibility/ dispersion stability is determined to demonstrate that a sufficient amount of the active substance is suspended in the spray liquid to give a satisfactory, homogeneous mixture during spraying. For the determination of mass of active substance still in suspension the validated analytical method (study code DNA5853) was used

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						(HPLC method). According to CIPAC MT 184 method the mean measured active suspensibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for Flufenacet – pre storage (the analysis were performed for active substance Flufenacet at high concentration in CIPAC Water D and low concentration in CIPAC Water D).
Spontaneity of dispersion Aclonifen (KCP 2.8.3.2)	CIPAC MT 160	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	In CIPAC Water A: 98.11% In CIPAC Water D: 96.66%	Y	Pomeroy, D. 2020	**Accepted** The spontaneity of dispersion is determined to show the preparation is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the Aclonifen using both CIPAC Water A nad CIPAC Water D before storage.
Spontaneity of dispersion Flufenacet	CIPAC MT 160	Aclonifen 540 g/L, Flufenacet 60 g/L, SC	In CIPAC Water A: 97.84% In CIPAC Water D:	Y	Pomeroy, D. 2020	**Accepted** The spontaneity of dispersion is determined to

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.2)		(Batch GLO-20F-2306A)	96.60%			show the preparation is rapidly dispersed when diluted with water. Acceptable limits: the mean measured minimum active spontaneity of dispersion or dispersibility must not be less than 60 % or greater than 105 %.. The above mentioned criteria were met for the Flufenacet using both CIPAC Water A nad CIPAC Water D before storage.
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for an SC formulation.	-	-	**Accepted**
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable as GLOB1310aH is a suspension concentrate.	-	-	**Accepted**
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required since neither a dust nor a powder	-		**Accepted**
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Mean of two results: 0.1885%	Y	Pomeroy, D. 2020	**Accepted** A wet sieve test is required for water dispersible products. The residue remaining on a sieve is determined after dispersion to ensure no unacceptable residue remains which might cause the blockage of nozzles or filters on

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						application equipment. Acceptable limits: Maximum 2 % retained on a 75 µm sieve. The above mentioned criteria was met (mean wet sieve residue was 0.1885%) for pre storage test item.
Dust content (KCP 2.8.5.2.1)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Attrition (KCP 2.8.5.3)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable as GLOB1310aH is a suspension concentrate.	-	-	**Accepted**
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable as GLOB1310aH is a suspension concentrate.	-	-	**Accepted**
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not applicable as GLOB1310aH is a suspension concentrate.	-	-	**Accepted**
Flowability (KCP 2.8.7.1)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	Aclonifen 540 g/L, Flufenacet 60 g/L, SC (Batch GLO-20F-2306A)	Poured Residue: 3.6505% Water Rinsed Residue: 0.1630% Acetone Rinsed Residue: 0.0036%	Y	Pomeroy, D. 2020	**Accepted** The data are required to demonstrate that the user can make use of the maximum amount of the preparation and that an excessive

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						amount of the material does not remain in the container. Acceptable limits: Maximum 5 % residue was met. The residue remaining in the commercial pack following recommended rinsing procedures is acceptable.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required as GLOB1310aH is a liquid.	-	-	**Accepted**
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant: no tank mix on the label.	-	-	**Accepted**
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant: no tank mix on the label.	-	-	**Accepted**
Adhesion to seeds (KCP 2.10.1)	-	-	GLOB1310aH is not used for seed treatment.	-	-	**Accepted**
Distribution to seed (KCP 2.10.2)	-	-	GLOB1310aH is not used for seed treatment.	-	-	**Accepted**
Other/special studies (KCP 2.11)	-	-	-	-	-	**Accepted**

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

GLOB1310aH is to be marketed in 0.25-0.5-1-5-10-15-20 litre containers. These containers are UN-approved and meet the ADR requirements. Storage stability was tested with commercial packaging. For resistance of the packaging material to its contents, a cross-reference is made to the physical and chemical studies performed with the packaging material.

As specified in the "Guidance document for the generation and evaluation of data on the physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009 of the EU Parliament and Council on placing plant protection products on the market" (final draft, July 2018), all rigid packaging types, apart from metal, are supported with no further data, regardless of the packaging using in the shelf-life study (except metal). Therefore, packaging containers can consist of other plastic materials besides HDPE, such as HDPE/PA, HDPE/F and HDPE/EVOH.
Please fin their specification below.

Table 0-1: Packaging information for 250 mL bottle

Type	**Description**
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 60 mm diameter x 125 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-2: Packaging information for 500 mL bottle

Type	**Description**
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 60 mm diameter x 185 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-3: Packaging information for 1L bottle

Type	Description
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-4: Packaging information for 2L container

Type	Description
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 106 mm width x 155 nm length x 189 mm height
Opening:	42 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-5: Packaging information for 3L container

Type	Description
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 160 mm width x 262 nm length x 115 mm height
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-6: Packaging information for 5 litre container

Type	**Description**
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 140 mm x 190 mm x 313 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-7: Packaging information for 10 litre container

Type	**Description**
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 179 mm x 240 mm x 375 mm
Opening:	63 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-8: Packaging information for 15 litre container

Type	**Description**
Material:	HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	Height: 311 mm, Width: 245 mm, Length: 294 mm
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Table 0-9: Packaging information for 20 litre container

Type	Description
Material:	HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Shape/size:	rectangular / approx. 263 mm width x 292 mm length x 372 mm height
Opening:	55 mm inner diameter
Closure:	polyethylene screw cap
Seal:	induction seal
Manner of construction	extruded
UN/ADR	compliant

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of product have been removed.

4.2.2 Effectiveness of the cleaning procedures (KCP 4.2)

The effectiveness of tank cleaning was assessed in one of the studies to determine the physicochemical properties of the product (Pomeroy D., 2020). The formulation was added to 8 L of water in the spray tank at the required application rate. After spraying, the tank was washed with three 400 mL water rinses. The collected residue was then assayed by HPLC-DAD.

It was concluded that three rinses with water allowed to reduce the concentration of Aclonifen to 0.00767% of the initial one.
It was concluded that three rinses with water allowed to reduce the concentration of Flufenacet to 0.00792% of the initial one.

Accepted
The formulation was added to 8 L of water in the spray tank at the required application rate. After spraying the tank was washed with three 400 ml water rinses followed by collection of remaining residue with 50 ml Acetonitrile. The collected residue was then analysed by HPLC-PDA. The method used for determination of active substances in the collected residue was validated in GLP Laboratory (in house validated methodology – study code DNA5653).
Three rinses with water allowed to reduce the concentration of Aclonifen to 0.00767% of the initial one.
Three rinses with water allowed to reduce the concentration of Flufenacet to 0.00792% of the initial one.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP2.1 2.3.1 2.3.3 2.4.1 2.4.2 2.5.1 2.5.2 2.6.1 2.7.2 2.7.3 2.7.4 2.8.2 2.8.3.1 2.8.3.2 2.8.5.1.2 2.8.7.2	Pomeroy, D.	2020	Determination of storage stability and shelf life specification data for a suspension concentrate formulation containing Aclonifen & Flufenacet stored at 40 °C ± 2 °C for eight weeks, in compliance with good laboratory practice. Laboratory: David Norris Analytical Laboratories Ltd. Study number: DNA5850 GLP Unpublished	N	Globachem NV
KCP 2.7.5	Pomeroy, D.	ongoing	A 2 years shelf life study at ambient temperature is currently ongoing at DNAL (study plan DNA5851); the results will be provided when available (October 2022).	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.2.1-01 (also covers KCP 2.2.2) Filed in Part C	Pomeroy, D.	2021	Theoretical certificate of explosive and oxidizing properties for a suspension concentrate for formulation containing aclonifen and Flufenacet. Laboratory: David Norris Analytical Laboratories Ltd. Study number: Certificate dated No GLP Unpublished	N	Globachem NV

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Aclonifen

Not applicable.

A 2.2 Flufenacet

Not applicable.